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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,342	03/06/2002	Kevin Burke	7601/80250	1549

7590 10/19/2005  
 Michael A. Sanzo  
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 Suite 401L  
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 Washington, DC 20006-1201

EXAMINER

PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/091,342

Applicant(s)

BURKE ET AL.

Examiner

Rebecca E. Prouty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 March 2005.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17-36 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 17-36 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/05.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

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Claims 1-16 have been canceled. Claims 17-36 are at issue and are present for examination.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/18/05 has been entered.

Applicants' arguments filed on 3/18/05, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Applicant's claim for the benefit of prior-filed applications 09/531,267 and 60/142,915 under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the

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art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunican et al. (WO 01/04322) in view of Möckel et al. (EP 1 096 013, see English equivalent document AU 200068075) or Dusch et al. (US PG-PUB 2005/0196848) and JP 09-244661.

Dunican et al. teach methods of making amino acids, in particular lysine and threonine, comprising fermentation of a *Corynebacterium glutamicum* which produces L-lysine, L-threonine, L-isoleucine, or L-tryptophan, in which the zwf gene (encoding a glucose-6-phosphate dehydrogenase subunit) of a Coryneform bacteria is overexpressed and the poxB gene of the bacterium is attenuated. Dunican et al. do not teach a zwf gene encoding SEQ ID NO:8 or 10 or a poxB gene encoding SEQ ID NO:5

JP 09-244661 teaches a *Brevibacterium flavum* zwf gene identical to SEQ ID NO:8.

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Möckel et al. and Dusch et al. teach a *Corynebacterium glutamicum* poxB gene encoding the protein of SEQ ID NO:5, methods for the attenuation of the expression of this gene in *Corynebacterium glutamicum* by integration mutagenesis using the plasmid pCR2.1poxBint and methods for making amino acids using the *Corynebacterium glutamicum* having the poxB gene attenuated therein.

Therefore, it would have been obvious to one of ordinary skill in the art to make a *Corynebacterium glutamicum* in which the zwf gene of JP 09-244661 is overexpressed and the poxB gene of the bacterium is attenuated as taught by Dunican et al. It would have been further obvious to use any of the specific *Corynebacterium glutamicum* strains listed by Dunican et al. on pages 6-7 as the strain to be modified and to then use these strains for the production of L-lysine, L-threonine, L-isoleucine, or L-tryptophan. Claims 18, 21, 26, and 31 specifically recite that the zwf gene used encodes SEQ ID NO:10. SEQ ID NO:10 differs from the gene of SEQ ID NO:8 disclosed in JP 09-244661 in the inclusion of 30 additional N-terminal amino acids. However, Dunican et al. teach that the natural N-terminus of the *Corynebacterium glutamicum* zwf gene has the sequence Xaa Xaa Xaa Xaa Xaa Pro Xaa Xaa Trp Xaa Asn Pro Leu Arg Asp and teach a *Corynebacterium glutamicum* zwf gene having this

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N-terminal amino acid sequence which includes a 29 amino acid N-terminal sequence following a GTG initiation codon and preceding an amino acid sequence identical to SEQ ID NO:8 except for a single substitution at amino acid 120 of SEQ ID NO:8. Thus the zwf gene of Dunican et al. encodes a protein identical to SEQ ID NO:10 except for an N-terminal Val residue and a single amino acid substitution at amino acid 150 of SEQ ID NO:10. It would have been obvious to one of skill in the art to modify the amino terminal GTG codon of the zwf gene of Dunican et al. to an ATG codon, as ATG is well known in the art to be the most preferred initiation codon in bacteria. Furthermore, it would have been obvious to one of skill in the art that the amino acid at position 150 of the gene of Dunican et al. could be either alanine as in the zwf gene of Dunican et al. or threonine as in the zwf gene of JP 09-244661 as the proteins are otherwise identical. As such using a zwf gene of SEQ ID NO:10 would have been obvious to one of ordinary skill in the art.

It is noted that the Dunican et al. (WO 01/04322) and Möckel et al. (EP 1 096 013) references were published after the filing date of applicants parent applications (09/531,269, 09/531,267 and 60/142,915). However, applications 09/531,269, 09/531,267 do not support the current claims as they do not describe zwf genes encoding the proteins of SEQ ID NOS:8 and 10.

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The provisional application is not in English and thus applicant cannot rely upon the this application to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17-36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/336,049. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference

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claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 17-36 and claims 1-6 of copending Application No. 10/336,049 are all directed to methods of making lysine, threonine, isoleucine or tryptophan comprising fermenting a bacterium in which the endogenous *poxB* gene is attenuated and a *zwf* gene is overexpressed. The claims differ in that Claims 17-36 herein recite that the bacterium is a *Corynebacterium glutamicum* transformed with a *zwf* gene of SEQ ID NO:8 or 10 and the attenuated *poxB* gene is SEQ ID NO:4 with an inactivating disruption of its sequence while in the copending application, the bacterium can be from any genus and the *zwf* and *poxB* genes can have any sequence. The portion of the specification in 10/336,049 that supports the recited bacteria and *zwf* and *poxB* genes includes embodiments that would anticipate claims 17-36 herein, e.g., wherein the bacteria are *Corynebacterium glutamicum*, wherein the bacteria are transformed with a *zwf* gene of SEQ ID NO:8 or 10 and wherein the attenuated *poxB* gene is SEQ ID NO:4 with an inactivating disruption of its sequence. Claims 17-36 cannot be considered patentably distinct over claims 1-6



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of copending Application No. 10/336,049 when there is are specifically recited embodiments that would anticipate claims 17-36. Alternatively, claims 17-36 cannot be considered patentably distinct over claims 1-6 of copending Application No. 10/336,049 when there are specifically disclosed embodiments in 10/336,049 that support claims 1-6 of that application and fall within the scope of claims 17-36 herein because it would have been obvious to one having ordinary skill in the art to modify the methods of claims 1-6 by selecting a specifically disclosed embodiment of bacterium , zwf gene and poxB gene disruption that supports that claim, i.e., wherein the bacteria are *Corynebacterium glutamicum*, wherein the bacteria are transformed with a zwf gene of SEQ ID NO:8 or 10 and wherein the attenuated poxB gene is SEQ ID NO:4 with an inactivating disruption of its sequence. One having ordinary skill in the art would have been motivated to do this because these embodiments are disclosed as being preferred embodiments within claims 1-6 of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 17-36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting

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as being unpatentable over claims 28, 29, 32, 33, 37, 38, 42, and 43 of copending Application No. 11/025,115. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 17-36 and claims 28, 29, 32, 33, 37, 38, 42, and 43 of copending Application No. 11/025,115 are all directed to methods of making lysine, threonine, isoleucine or tryptophan comprising fermenting a bacterium in which the endogenous *poxB* gene is attenuated and a *zwf* gene is overexpressed. The claims differ in that Claims 17-36 herein recite that the bacterium is a *Corynebacterium glutamicum* transformed with a *zwf* gene of SEQ ID NO:8 or 10 and the attenuated *poxB* gene is SEQ ID NO:4 with an inactivating disruption of its sequence while in the copending application, the bacterium can be from any genus, the *zwf* gene is specifically that encoding SEQ ID NO:10 and the *poxB* gene can

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have any sequence. The portion of the specification in 11/025,115 that supports the recited bacteria and poxB genes includes embodiments that would anticipate claims 17-36 herein, e.g., wherein the bacteria are *Corynebacterium glutamicum*, and wherein the attenuated poxB gene is SEQ ID NO:4 with an inactivating disruption of its sequence. Claims 17-36 cannot be considered patentably distinct over claims 28, 29, 32, 33, 37, 38, 42, and 43 of copending Application No. 11/025,115 when there is are specifically recited embodiments that would anticipate claims 17-36. Alternatively, claims 17-36 cannot be considered patentably distinct over claims 28, 29, 32, 33, 37, 38, 42, and 43 of copending Application No. 11/025,115 when there are specifically disclosed embodiments in 11/025,115 that support claims 28, 29, 32, 33, 37, 38, 42, and 43 of that application and fall within the scope of claims 17-36 herein because it would have been obvious to one having ordinary skill in the art to modify the methods of claims 28, 29, 32, 33, 37, 38, 42, and 43 by selecting a specifically disclosed embodiment of bacterium and poxB gene disruption that supports that claim, i.e., wherein the bacteria are *Corynebacterium glutamicum* and wherein the attenuated poxB gene is SEQ ID NO:4 with an inactivating disruption of its sequence. One having ordinary skill in the art would have been motivated to do this because

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these embodiments are disclosed as being preferred embodiments within claims 28, 29, 32, 33, 37, 38, 42, and 43 of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rebecca Prouty  
Primary Examiner  
Art Unit 1652